



Imaging Data Exchange Implementation Guide

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1.0 Introduction

This Implementation Guide is intended as an extension of the Query-Based Document Exchange Implementation Guide to address the capability to exchange DICOM imaging exams. Historically, imaging data has not been treated in the same fashion as data that can be represented in a textual format, such as physician notes, discrete lab values, and problem lists, largely due to the significantly larger storage and bandwidth requirements of digital imaging data. Nonetheless, the same need for exchanging this information exists. Recently there has been a convergence of technical solutions so that imaging data may be exchanged over the Internet in much the same fashion as other healthcare data contained in clinical documents. A few technical differences remain, which can be addressed by the addition of a few transactions specific to imaging data that are well-aligned with existing standards.

As an extension to the existing Implementation Guide, this document applies to Carequality Implementers and their Carequality Connections (CCs) who exchange imaging data under the Carequality Elements. By listing imaging exchange endpoints in the Carequality Directory, an Implementer or CC asserts that it is compliant with the requirements of the Query-Based Document Exchange Implementation Guide, in general, and with this Implementation Guide, for the specific use of such imaging endpoints. Specifically, this document does not override or replace any provision of the Query-Based Document Exchange Implementation Guide in Sections 2 through 6 and replaces the provisions in Sections 7 and 8 only with respect to the operation of imaging exchange endpoints. For example, implementers must respect the Permitted Purposes and assert which Permitted Purpose applies to a request for imaging data. Furthermore, an imaging implementer must have completed any requirements for participation as an Implementer or CC under the Carequality Elements.

Notwithstanding the requirements of the above paragraph, there are some terms within Sections 2-6 of the IG that require clarification in the context of image data exchange. Sections 2-6 of this document will reference Sections 2-6 of the Query-Based Document Exchange Implementation Guide and will then provide clarification.

2.0 Definition of Roles

See the Query-Based Document Exchange Implementation Guide, Section 2, Definition of Roles.

With respect to Section 2.3, Record Locator Service (RLS), an Implementer or CC that plays the role of an RLS MAY provide information about the location of clinical documents, imaging studies, or both. For clarity, an RLS MAY provide information on the location only of documents, or only of imaging studies.

3.0 Customizable Principles of Trust

See the Query-Based Document Exchange Implementation Guide, Section 3, Customizable Principles of Trust.

With respect to Section 3.2, Full Participation, an Implementer or CC that plays the role of Query Responder for this Use Case, and chooses to honor queries for a particular Permitted Purpose, MUST honor queries for that Permitted Purpose for both imaging studies and documents, if it has endpoints listed in the Carequality Directory supporting the exchange of both data formats.

4.0 Non-Discrimination

See the Query-Based Document Exchange Implementation Guide, Section 4, Non-Discrimination.

With respect to Section 4.4 Access Policy Assertions the rules governing document retrieval apply in full to image exchange

With respect to Section 4.4 upon receiving a query without an indication of a signed consent document, the query responder will request additional documentation in response or will not release a patient's information, including an imaging exam to the query initiator.

5.0 Performance Measures

See the Query-Based Document Exchange Implementation Guide, Section 5, Performance Measures.

To the extent that Section 5, Performance Measures, requires an Implementer to report measures involving documents, Implementers who support image exchange SHALL report to Carequality the number of relevant imaging studies in lieu of the number of relevant documents. Implementers who support both image exchange and document exchange SHALL report to Carequality the number of relevant imaging studies and the number of relevant documents separately.

6.0 Evidence of Compliance

See the Query-Based Document Exchange Implementation Guide, Section 6, Evidence of Compliance.

With respect to Section 6, Evidence of Compliance, image exchange implementers will complete a non-production test with one other Implementer whose connectivity relies on software provided by a different technology vendor or provider (the Test Partner). Specifically, matching patients must be found, at least one of each mandatory imaging document element as specified in Section 8.X must be available, and one or more images must be retrieved.

7.0 Imaging Exchange Use Case

7.1. Background

This use case describes the actors, transactions and requirements to enable the exchange of imaging data between and among networks as an extension of the Query-Based Document Exchange Use Case. This section focuses on desired functionality following the model in Query-Based Document Exchange Implementation Guide, Section 7.

The use case is written to enumerate all flows (both alternate and error) that are possible, given the underlying transactions. The decisions regarding which flows are considered in and out of scope for Carequality, and required/optional for roles/actors, are made in section 8.0, Imaging Technical Requirements and Guidance.

In sections below, we will refer to DICOM Key Object Selection (KOS) documents that contain a manifest of DICOM images that will be retrieved.

7.2. Use Case: Retrieve Images Use Case

In this use case, a user (acting through an Initiating Imaging Gateway) queries Responding Imaging Gateways for patient medical images, using the IHE XCPD, XCA, and XCA-I profiles.

7.2.1. Actors

1. Initiating Imaging Gateway (multiplicity of 1)
2. Responding Imaging Gateway (multiplicity of 1..*)
3. Initiating Gateway (multiplicity of 1)
4. Responding Gateway (multiplicity of 1..*).
5. Participant Gateway Directory, i.e. phonebook (e.g. FHIR, UDDI or other) (multiplicity of 0..*)
6. Record Locator Service (multiplicity of 0..*)

7.2.2. Assumptions

1. Reference assumptions from Section 7.2.2 of Query-Based Document Exchange Implementation Guide.
2. The Initiating Imaging Gateway and Responding Imaging Gateway agree on transport level details (specified elsewhere in this document) that allow for the following:
 - a. Secure messaging over TLS.

7.2.3. Pre-conditions

1. Reference assumptions from Section 7.2.3 of Query-Based Document Exchange Implementation Guide.
2. The Initiating Gateway is configured to search for and retrieve DICOM KOS documents from one or more Responding Gateways.
3. The Responding Gateway is able to search for and retrieve DICOM KOS documents upon request from the Initiating Gateway.
4. The Initiating Imaging Gateway knows the patient's demographics.

5. (Nominal flow only) The Initiating Imaging Gateway has the desired service endpoint(s), and optionally the HCIDs, for some number of Responding Imaging Gateways that may be queried for patient images.
6. Responding Imaging Gateways are able to respond to requests for DICOM images through integration with XDS-I Imaging Document Source systems or by other mechanisms.

7.2.4. Use Case Steps – “Nominal Flow”

Each of the following steps may be repeated for each Responding Gateway of interest.

1. Reference steps 1, 2, 3, 4 in Section 7.2.4 of Query-Based Document Exchange Implementation Guide.
2. Append to step 5 from Section 7.2.4 of Query-Based Document Exchange Implementation Guide.
 - a. For the Imaging Use Case, the Initiating Gateway may request only DICOM KOS documents from a Responding Gateway or may retrieve different document types and filter the response.
3. Reference step 6 from Section 7.2.4 of Query-Based Document Exchange Implementation Guide.
4. The Initiating Imaging Gateway or system driving the Initiating Imaging Gateway parses the DICOM KOS document and decides which image or images are to be retrieved.
5. The Initiating Imaging Gateway sends an IHE Cross Imaging Gateway Retrieve Imaging Document Set [RAD-75] request to the Responding Imaging Gateway to retrieve desired images. The request includes the document/repository/community IDs at the Responding Imaging Gateway. See IHE RAD TF-3: 75.
6. The Responding Imaging Gateway retrieves the requested images from its repositories and returns a RAD-75 response containing the images.

7.2.5. Post-conditions

1. Reference statements 1 and 2 from Section 7.2.5 in Query-Based Document Exchange Implementation Guide.
2. The Initiating Imaging Gateway has obtained the desired images as known by each Responding Imaging Gateway.

7.2.6. Alternate Flows

1. Reference statements 1 – 5 from Section 7.2.6 in Query-Based Document Exchange Implementation Guide.
2. Statements 1 – 5 from Section 7.2.6 in Query-Based Document Exchange Implementation Guide describe how an Initiating Gateway can obtain endpoints for Responding Gateways. Those five statements apply equally to an Initiating Imaging Gateway.
3. Reference statements 6 – 32.

7.2.7. Error Flows

1. Reference statements 1 – 19 in Query-Based Document Exchange Implementation Guide.

8.0 Technical Requirements and Guidance – Imaging

Note that for this document, Query Initiator encompasses both an XCA Initiating Gateway as well as an XCA-I Initiating imaging Gateway. Likewise, the Query Responder includes both the XCA Responding Gateway and XCA-I Responding Imaging Gateway. That means the Query Responder is responsible for providing access for patient discovery, retrieval of KOS objects and retrieval of DICOM images.

8.1.Roles

8.1.1. Query Initiator

Reference Section 8.1.1 in Query-Based Document Exchange Implementation Guide.

CONF-10xx: Each Query Initiator MUST provide an XCA-I Initiating Imaging Gateway actor and support the required transactions as described in this Technical Requirements and Guidance section.

8.1.2. Query Responder

Reference Section 8.1.2 in Query-Based Document Exchange Implementation Guide.

CONF-10xx: Each Query Responder MUST provide an XCA-I Responding Imaging Gateway actor and support the required transactions as described in this Technical Requirements and Guidance section.

8.1.3. Record Locator Service

Reference Section 8.1.3 in Query-Based Document Exchange Implementation Guide.

8.2.Overall Query Workflow

Reference all of Section 8.2 in Query-Based Document Exchange Implementation Guide.

8.2.1. Retrieve Images Use Case Flow Requirements

This table shows the required flows from the Imaging use case for the Initiating Gateway (IG) and Responding Gateways (RG).

Flow	IG/RG	Requirements
Nominal Flow	IG	Required
Nominal Flow	RG	Required

8.2.2. XCA-I Gateway Requirements

CONF-10xx: All requirements pertaining to the IHE Rad Technical Framework, unless otherwise specified, refer to IHE Rad TF, Revision 17.0 (July 27, 2018).

The XCA-I Initiating Imaging Gateway is required to support IHE Rad Transaction 75 and all related requirements. IHE Rad Transaction 69 is not required as the initiating community will define the mechanism for triggering the RAD 75 transaction.

The XCA-I Responding Imaging Gateway is required to support IHE Rad Transaction 75 and all related requirements. IHE Rad Transaction 69 is not required as the responding community will define the architecture needed to support the retrieval of images.

8.2.3. Hosting and Retrieving Policy Instance Documents

Requirements for Initiating Gateway and Responding Gateway are covered by prior reference to Section 8.2 of Query-Based Document Exchange Implementation Guide.

CONF-10xx: An Imaging Query Initiator does not host IACP documents and does not include IACP document unique id's in requests for image data.

CONF-10xx: An Imaging Query Responder does not have access to IACP documents.

CONF-10xx: An Imaging Query Responder assumes that the user requesting images has permission to retrieve the images by virtue of having retrieved the DICOM KOS document through an Initiating Gateway.

8.3. Directory Services

Reference all of Section 8.3 in Query-Based Document Exchange Implementation Guide.

8.3.1. Retrieve Images Use Case Flow Requirements

Initiating Imaging Gateway (IG) has these requirements.

Flow	IG	Requirements
Nominal Flow	IG	Required. Nominal flow assumes Initiating Gateway has already obtained endpoint(s) in some way.
Find Service Endpoint by HCID	IG	Optional - this feature is not currently in scope and is not tested by Carequality.
Find Service Endpoint by search parameters	IG	Optional - this feature is not currently in scope and is not tested by Carequality.
Find Service Endpoint by external directory	IG	Optional
Find Service Endpoint – multiple Responding Gateways found	IG	Required – Initiating Gateways MUST be able to support communicating with multiple gateways. Informative: This guide does not specify a processing model for communicating with multiple Responding Gateways, e.g. sequential or parallel, aggregation of results, human intervention, etc.
Use of directory to obtain information other than Responding Gateway endpoints	IG	Optional

Responding Gateway not found	IG	Optional - this feature is not currently in scope and is not tested by Carequality.
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8.4. Security and Transport

Reference all of Section 8.4 in Query-Based Document Exchange Implementation Guide.

8.4.1. Retrieve Images Use Case Flow Requirements

This table shows the required flows from the Retrieve Images use case for the Initiating Imaging Gateway (IG) and Responding Imaging Gateways (RG).

Flow	IG / RG	Requirements
Nominal Flow	IG / RG	Required. Nominal flow assumes all security aspects function successfully.
Error in SOAP request	IG / RG	Required
Error in SOAP response	IG	Required
Access denied	RG	Does not apply. RIG will not enforce access controls.
Access denied	IG	Does not apply. RIG will not enforce access controls.
Access partially denied	RG	Does not apply. RIG will not enforce access controls.
Access partially denied	IG	Does not apply. RIG will not enforce access controls.
Additional permission needed	RG	Does not apply. RIG will not enforce access controls.
Additional permission needed	IG	Does not apply. RIG will not enforce access controls.

8.5. Patient Discovery

Reference all of Section 8.5 in Query-Based Document Exchange Implementation Guide.

8.6. Record Locator Services

Reference all of Section 8.6 in Query-Based Document Exchange Implementation Guide.

8.6.1. Retrieve Images Use Case Flow Requirements

Initiating Imaging Gateway (IIG) has these requirements.

Flow	IG	Requirements
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Health data locators returned	IG	Required. Initiating Gateways MUST be able to process responses that indicate Health Data Locators, and MAY make use of them with ITI-56 transactions.
Asynchronous patient location query	IG	Not permitted. See Patient Discovery Detailed Requirements.
Patient location query returns no patient locations	IG	Required
Responding Gateway is not a health data locator for this patient	IG	Required
Responding Gateway cannot process patient location query for internal reasons	IG	Required

8.7. Retrieve Images

Reference all of Section 8.7 (Query-Based Document Exchange Implementation Guide, Document Query and Retrieve) in the context of the Initiating Gateway searching for and retrieving a DICOM KOS document.

8.7.1. Use Case Flow Requirements

The table in Section 8.7.1 of Query-Based Document Exchange Implementation Guide is used as written in the context of searching for and retrieving the DICOM KOS document. The table below defines requirements for the Initiating Image Gateway (IIG) and Responding Imaging Gateway (RIG).

Flow	IG / RG	Requirements
Nominal Flow: Step 4	IG	Required
Nominal Flow: Step 5	IG	Required
Nominal Flow: Step 6	RG	Required

8.7.2. XCA Gateway Requirements

CONF-10xx: An Initiating Gateway MUST support the metadata requirements for the DICOM KOS document defined in IHE RAD TF Vol 3: 4.68.

CONF-10xx: A Responding Gateway MUST support the metadata requirements for the DICOM KOS document defined in IHE RAD TF Vol 3: 4.68.

CONF-10xx: An Initiating Gateway MUST implement the appropriate requirements in IHE RAD TF Vol 3: 4.75.

CONF-10xx: A Responding Gateway MUST implement the appropriate requirements in IHE RAD TF Vol 3: 4.75.

8.7.3. Document Metadata Requirements

Document metadata requirements are extended to support the DICOM KOS document.

Document Metadata	Reference	scheme OID
classCode	HITSP C80, version 2.0.1, table 2-144	2.16.840.1.113883.6.1
eventCodeList	IHE RAD TF Vol 3: 4.68.4.1.2.3.2	
formatCode	IHE RAD TF Vol 3: 4.68.4.1.2.3.2	1.2.840.10008.2.6.1
typeCode	IHE RAD TF Vol 3: 4.68.4.1.2.3.2 This is different from the standard Query Use Case in this document. This constraint on typeCode is specific to the imaging use case.	

8.7.4. XCA-I Profile Options

CONF-10xx: An XCA-I Initiating Gateway MUST NOT use the Asynchronous Web Services Exchange option.

8.7.5. On-Demand Documents

Already included by reference to Query-Based Document Exchange Implementation Guide, Section 8.7.

8.7.6. Supported Queries

Already included by reference to Query-Based Document Exchange Implementation Guide, Section 8.7.

8.7.7. Query Behavior

Already included by reference to Query-Based Document Exchange Implementation Guide, Section 8.7.

8.7.8. Error Handling

Already included by reference to Query-Based Document Exchange Implementation Guide, Section 8.7.

8.7.9. Including Images from Facilities Covered by 42 CFR Part 2

Already included by reference to Query-Based Document Exchange Implementation Guide, Section 8.7.

9.0 Issues and Questions

9.1. Open Issues and Questions

Imaging-001: How does the XCA-I Initiating Imaging Gateway find the Patient Identifier to search for the DICOM KOS document?

- The first draft of this document had separate actors for the Initiating Gateway and Initiating Imaging Gateway. This draft combines those actors into a single system.

Imaging-002: How do the XCA-I Initiating and Responding Imaging Gateways check and enforce that the end user has authorization to retrieve the requested DICOM images?

- The XCA-I gateways rely on the authorization that is implemented by the XCA gateways when the XCA gateways interact to search for and retrieve the DICOM KOS document. Without access to this manifest, the XCA-I Initiating Imaging Gateway would only be able to perform random queries to try to identify images by DICOM UIDs. The Responding Imaging Gateway may implement a scheme to limit random guesses that it receives.

Imaging-003: Does this scheme support DICOM WADO retrieves?

- The XCA-I Integration Profile only supports the RAD-75 transaction between the gateway systems.

Imaging-004: Can the Responding Imaging Gateway rely on having a complete XDS-I.b infrastructure available in its community?

- The architecture present in the responding community is defined by that community. Responding Gateway systems will have to work with a specific community to determine how the gateway will be able to support the required transactions?

Imaging-005: How does the XCA Responding Gateway search for and retrieve DICOM KOS documents?

- This is similar to the question of how the XCA Responding Gateway is able to search for and retrieve any kind of document. It is the responsibility of the XCA Responding Gateway to work within the defined community to provide support for the DICOM KOS document type. If that

integration is not possible, that Responding Gateway will not be able to support the Imaging Exchange use case.

Imaging-006: What are the requirements for storage retention when images are imported?

- Image import defined in this document is similar in scope to image import using CDs. It is recognized that importing data over a network might allow more imaging studies to be imported than would fit on a single CD; that is, one might encounter higher volume. However, the storage retention policies for the importing system should be driven by local legal requirements and institutional policies. These should not be different than in a CD based system.

Imaging-007: Can sending sites be required to validate DICOM images?

- One goal of this Implementation Guide is to replace CD based import systems with a network solution. Importing images from CDs is difficult when the CDs contain invalid DICOM images. The problem is exacerbated because the importing institution is presented with a CD that was generated by an unknown institution with no point of contact. ***Are there constraints/expectations that can be put on the sending systems that participate in this program?***

Imaging-008: Should the IG define a process for normalizing procedure codes?

- Normalization of procedure codes through the gateways would simplify the search process initiated by the Initiating Gateway. That would allow the Initiating Gateway to specify a coded value and reduce the scope of the search. That work is not defined in the scope of this IG. No comment / commitment is made concerning a future version.

9.2. Resolved Issues and Questions

10.0 Explanatory Material – Non Normative

10.1. Use Cases

10.1.1. Patient Referral, CD Replacement

The key use case defined for this document is patient referral involving prior imaging procedures. In a CD based system, the patient brings a CD to the appointment, and a staff member imports data on the CD into a PACS or equivalent system. The specifications defined in this document are intended to support the following:

When	Patient arrives at a referral appointment. Patient has had prior imaging procedures at another institution in a different care community.
Where	Takes place at the office/institution to which the patient was referred.
Why	Care giver wants to see prior images for any of a number of reasons: <ul style="list-style-type: none">• Avoid retakes• Compare priors to images recently taken• View historical images even with no current imaging
How	Patient present at the imaging department where a staff member interacts with the patient to retrieve (pull) images from another location and import them into the local PACS or equivalent system.
Actor	The person performing the import operation is most likely a staff member in the imaging department. Once the images have been imported into the PACS, they are available for viewing through that system.

10.2. DICOM Object Import Guidelines

The act of importing an imaging study into a PACS normally requires more work than just pushing the images in directly as if they were produced by a local modality. Values found in fields such as, but not limited to, Patient Identifier, Study ID, and Accession Number may have to be harmonized with local data to prevent conflicts and/or to support viewing software. A system that needs to import such images will likely already have a procedure in place for CD import. It is imagined that systems importing images over a network will use existing procedures or extend those procedures. This IG does not call out or require any specific procedure or policy to guide the import process and data harmonization.

10.3. Generation of DICOM Key Object Notes

DICOM KOS objects are used the mechanism to specify the images that the system in the Responding Community wishes to export. These images could encompass the complete imaging study or a subset as defined by the original institution. In the CD example, it is most likely that all of the images for a procedure are exported with further review by a radiologist. This same model is possible and appropriate for network exchange. A DICOM KOS object that references all of the images in the imaging study can be automatically generated and used as the basis for export. A radiologist is not required to define a subset of images. Should an institution include that step as part of their normal practice, the importing system may benefit and only present the images that were designated by the original system.

10.4. Responding Community XDS-I.b Infrastructure

The IHE XCA-I profile assumes the responding community will have a full XDS-I.b infrastructure. This IG only specifies the transactions between the gateways and does not specify the implementation in the responding community. A Responding Gateway can take advantage of an XDS-I.b infrastructure if one exists. For those communities where that infrastructure is not present, the Responding Gateway will provide whatever components are necessary. Note that this IG combines all gateway operations into a single system. These gateways are assumed to be in existence today with the ability to support the backend infrastructure. For example, rather than generating all KOS objects in advance and storing those in a Document Repository, the system implementing the Responding Gateway could have a link to a PACS and generate KOS objects on demand.